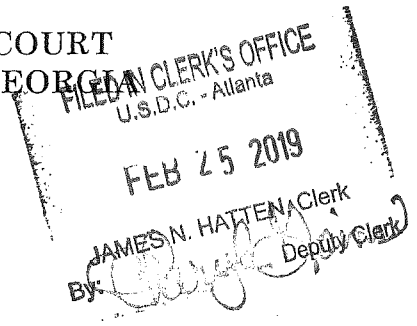
IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION



UNITED STATES OF AMERICA ex rel. AMY TYSON Relator, v. GEORGIA PAIN MANAGEMENT, P.C., SAMSON PAIN CENTER, P.C., and JAMES ELLNER, M.D. Defendants.	)	Civil Action No. 1:18-cv-5220-LMM Jury Trial Demanded FILED UNDER SEAL

FIRST AMENDED COMPLAINT

The United States of America, by and through Relator Amy Tyson, brings this action under 31 U.S.C. §§ 3729-3732 (False Claims Act "FCA") to recover all damages, penalties, and other remedies established by the FCA on behalf of the United States and Relator and would show the following:

JURISDICTION AND VENUE

1. This action arises under the FCA, 31 U.S.C. § 3729, *et seq*.

2. This court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) in that Defendants live in this jurisdiction, do or transact business in this jurisdiction, and portions of the violations of the FCA described herein were

carried out in this district.

3. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732(a) and (b).

4. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c) and under 31 U.S.C. § 3732(a).

THE PARTIES

5. Defendant Georgia Pain Management, P.C. ("GPM") corporate office is located at 120 Stone Bridge Parkway, Suite 420, Woodstock, Georgia 30189.

6. Defendant Samson Pain Center, P.C. ("SPC") corporate office is located at 120 Stone Bridge Parkway, Suite 420, Woodstock, Georgia 30189.

7. Defendant James Ellner, M.D. is the owner, Chief Executive Office, Chief Financial Officer, and Secretary for Georgia Pain Management, P.C. and Samson Pain Center, P.C.

8. Relator Tyson holds a Certificate for Medical Assisting and was the claims specialist overseeing the appeals for GPM and SPC. Relator had worked at GPM and SPC for 2 years until her termination in June 2018.

THE MEDICARE PROGRAM

9. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq., establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program. The Secretary of the United States Department of Health and Human Services ("HHS") administers the Medicare Program through the

Centers for Medicare and Medicaid Services ("CMS"), a component of HHS.

10. The Medicare program consists of several parts. Medicare Part A provides basic insurance for the costs of hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). Medicare Part B is a federally subsidized, voluntary insurance program that covers certain non-hospital medical services and products including the treatments at issue in this complaint. 42 U.S.C. § 1395(k), 1395(i), 1395(s). Reimbursement for Medicare claims is made by the United States through CMS. CMS, in turn, contracts with private insurance carriers to administer and pay Medicare Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395(u). In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994).

11. In order to receive Medicare funds, enrolled suppliers, including Defendants, together with their authorized agents, employees, and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the states expressly state that a provider must certify that it is in compliance with all federal and state statutes and regulations in order to receive payment from Medicare. 42 C.F.R. § 455, et seq.

12. Among the rules and regulations which enrolled suppliers, including Defendants, agree to follow are to: (1) bill Medicare for only those covered services which are medically necessary; (2) not bill Medicare for any services or items which

were not performed or delivered in accordance with all applicable policies, nor submit false or inaccurate information relating to provider costs or services; (3) not engage in any act or omission that constitutes or results in over-utilization of services; (4) be fully licensed and/or certified under the applicable state and federal laws to perform the services provided to recipients; (5) comply with state and federal statutes, policies and regulations applicable to Medicare; and (6) not engage in any illegal activities related to the furnishing of services to recipients.

13. At all times relevant to this Complaint, Defendants were participating as Medicare providers.

14. At all times relevant to this Complaint, Medicare constituted and continues to constitute a significant source of revenue for Defendants.

15. Defendants submitted or caused to be submitted false claims for payment to Medicare for services and supplies.

FACTUAL ALLEGATIONS

16. During Relator's employment, she came across numerous FCA violations.

I. ASC

17. Dr. Ellner makes sure to enrich himself by referring patients to SPC, which is the Ambulatory Surgical Center ("ASC"). He also uses the ASC to unbundle charges and to obtain compensation for procedures or office visits Medicare would not compensate for at an ASC. To Dr. Ellner, the ASC is just an

extension of the office.

A. The ASC Is A Kickback

18. The Medicare and Medicaid Fraud and Abuse Statute ("Anti-Kickback Statute" or "AKS"), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1977. The AKS arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically inappropriate, unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

19. The AKS prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute ascribes liability to both sides of an impermissible kickback relationship.

20. Essentially, if just one purpose of the payment was to induce future referrals, the Medicare statute has been violated. This is true even if the doctor performs some medical service for the money. It is not even required that it be the primary purpose—just one purpose of the payment. In other words, a defendant can

have 99 lawful reasons to enter a relationship, but if one other reason is to expect referrals, it is illegal. It is irrelevant if the funds would have been spent anyway or that Medicare funds were not used to make the illegal payment.

21. Claims for reimbursement for services that result from kickbacks are rendered false under the FCA. 42 U.S.C. § l320a-7b(g). It is not just the claims tied to the referring physician, but all claims that in any way relate to the referred patient. This would include medicine, labs, procedures, and a host of other related charges.

22. Compliance with the AKS is a precondition to participation as a health care provider under the Medicare program. Compliance with the Stark and AKS is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare and other federal health care programs.

23. Either pursuant to provider agreements, claim forms, or other appropriate manner, physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the AKS.

24. Kickbacks are at the core of the Government medical insurance system. The financial incentive to refer patients completely undermines "'the functioning of the system as a whole[.]'" Two years ago in a Statement of Interest of the United States of America, the DOJ wrote: "The prohibition against kickbacks is a core requirement whose violation eviscerates the value of the service the Government has

bargained for: an unbiased determination by a medical provider that a certain medical procedure, device, or drug is 'reasonable and necessary' for the treatment of a patient." Statement of Interest of the United States of America in Response to Defendants' Motion to Dismiss, *U.S. ex rel. Wood v. Allergan, Inc.,* Civil Action No. 10-CV-5645, at 4 (Oct. 19, 2016). The DOJ then quoted: "'Kickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole .... If providers could demand payment for claims resulting from kickback violations, then the AKS would be meaningless legislation.'" *Id.* (quoting *U.S. ex rel. Westmoreland v. Amgen, Inc.,* 812 F.Supp.2d 39, 54-55 (D. Mass. 2011)).

25. The Eleventh Circuit was one of the first Courts in the modern era to find that kickbacks cause claims to be false under the FCA. *U.S. v. Killough, 848 F.2d 1523* (11th Cir. 1988). The Eleventh Circuit was also a leader in finding that kickback violations related to Medicare claims cause the claims to be forfeit. *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.,* 423 F.3d 1256, 1259-1260 (11th Cir. 2005). It found that compliance with AKS is required for payment under federal healthcare programs. *Id.*

26. GPM has an ironclad policy that ALL outpatient surgical cases must go to the ASC. Here, the purpose of the ASC is not to assist in surgeries, but rather to enrich the doctor with kickbacks, upcoding, unbundling, and a variety of other FCA

violations. It is a cesspool of illicit profits. And, all those profits should be forfeit for the layers and layers of kickbacks.

27. One would be hard-pressed to find an ASC that was more replete with kickbacks than GPM's ASC. GPM receives remuneration for each patient referred to SPC. One category of kickbacks involves remuneration in the form of ASC investment income. There is a putative safe harbor that covers this type of income. However, in order to meet the safe harbor, the ASC has to be a completely separate entity from the practice and the practice cannot unbundle procedures by performing them in the ASC, but falsely claiming the procedure was done in the office (which is also a separate FCA violation).

B. ASC Is Not Separate From The Practice

28. Under the Social Security Act, providers furnishing surgical procedures to Medicare beneficiaries in an ASC may receive reimbursement for facility services provided the ASC complies with regulatory standards promulgated by the Department of Health and Human Services. 42 U.S.C. §1395k(a)(2)(F)(i). To this end, the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") has released regulations defining those conditions an ASC must meet in order to participate in the Medicare program—effective May 18, 2009. See 42 C.F.R. §416.1(b). One of the "basic requirements" set forth by CMS is that the ASC satisfies the regulatory definition for ASC. 42 C.F.R. §416.25(a).

The regulatory definition for ASC reads in pertinent part: "ASC means **any distinct entity** that operates **exclusively for the purpose of** providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following admission." 42 C.F.R. §416.2 (emphasis added). CMS has clarified the scope of this definition, stating: "The regulatory definition of an ASC **does not allow the ASC and another entity, such as an adjacent physician's office, to mix functions and operations in a common space** during concurrent or overlapping hours of operations." Ctrs for Medicare & Medicaid Servs., Ambulatory Surgical Centers (last modified Apr. 24, 2018), https://www.cms.gov/Medicare/Provider-Enrollment-andCertification/CertificationandComplianc/ASCs.html. (emphasis added).

29. In addition, the safe harbor does not apply if the entities are not separate. "Ambulatory surgical centers. As used in section 1128B of the Act, "remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, **whose operating and recovery room space is dedicated exclusively to the ASC**...." 42 CFR § 1001.952(r) (emphasis added). In addition to not meeting the definition of an ASC (and thereby forfeiting all billing to the ASC), SPC fails to meet the safe harbor requirement of exclusive use.

30. SPC and GPM mix a spectrum of functions and operations in a common space during overlapping hours of operation. Specifically, the staff for GPM and the ASC are shared between the two entities. The waiting room is shared by both operations. Patients have to walk through the GPM to get to the ASC. Additionally, the billing is shared with the physician's office. Patients are roomed in the ASC exam rooms in SPC prior to their procedure for an office visit. GPM bills for these office visits with GPM as the service location instead of SPC as indicated by the use of place of service "11" (i.e., physician's office) instead of place of service "24" (i.e., ASC).

31. GPM selects the place of service "11" to receive payment for services that would otherwise be denied. These visits are inclusive to the procedures and would be considered pre-operative work up prior to the procedure performed.

32. The credit card statements also show that all supplies are purchased with the same American Express card under the GPM name. Both GPM and SPC also have shared phone lines. In fact, the ASC does not have a separate telephone number for patients to call and both have the same exact mailing address.

C. ASC Discriminated Against Medicaid Beneficiaries

33. To receive those protections afforded by the safe harbor, both the entity and the physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

42 C.F.R. § 1001.952(r)(2)(vi). This nondiscrimination provision extends to patients receiving assistance through the Medicaid program, a federally assisted grant program for the States that provides coverage to children, the blind, the elderly, and disabled individuals whose income and resources are not sufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396; 42 C.F.R. § 430.0; 42 U.S.C. § 1396-1396v.

34. Dr. Ellner—the sole owner and operator of SPC—discriminated against Medicaid beneficiaries by refusing to accept their insurance and by forcing them to pay out-of-pocket for his services. Dr. Ellner specifically targeted Medicaid patients in this respect, as he accepted all forms of private insurance.

D. Procedures Unnecessarily Performed In ASC In Order To Unbundle Office Visits

35. Dr. Ellner performed office visits and trigger point injections ("TPI") and many other procedures at the ASC. The office visit portion was billed as if conducted in-office. The TPI portion (or other procedure) was billed through the ASC. By fraudulently billing the office visit as if conducted in-office, GPM filed false claims and received reimbursement for services to which it was not entitled. Moreover, by performing the procedure in the ASC instead of the office, GPM recouped a larger rate of reimbursement because the fees associated with procedures performed in the ASC exceed those performed in-office. Performing the procedures in the ASC as opposed to the office provided no additional benefit to the Medicare

beneficiary. The only person who benefited was the physician-investor in the ASC, Dr. Ellner.

II. The Office Visits Billed On The Same Day As The Procedures Were Inclusive Of The Procedure

36. GPM wrongly billed office visits that were inclusive of the procedures billed on the same day. GPM submitted false claims for payment for these office visits with CPT modifier 25. The 25 modifier indicates that the office visit was separately reimbursable and unrelated to the procedure performed on the same date of service. When a provider appends the 25 modifier to an office visit, they are stating that the office visit was completely unrelated to the procedure performed on the same day. This was not the case for GPM. Dr. Ellner was well aware that the visits and procedures were directly related to each other, yet he ordered the staff to append the 25 modifier in the hope that Medicare would not ask for a chart review.

37. Cases of factual falsity in medical billing include cases where the provider fragments bundled procedure codes and bills for the component procedure codes separately to receive higher reimbursement from federal health care programs—a practice commonly known as "unbundling." See e.g., *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 638, 638 n.4 (6th Cir. 2003) (discussing unbundling theory). . Some examples follow:

38. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]; CAHABA # [redacted]: Dr. Ellner coded the September 10,

2015 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed at the bottom of the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the November 24, 2015 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the June 13, 2016 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. On May 15, 2017, Dr. Ellner coded the office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically

at this office visit. Dr. Ellner coded the October 26, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

39. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]: Dr. Ellner coded the May 9, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the June 14, 2016 office visit as an established office visit with CPT code 99213 with a 25. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner code the (November 18, 2016) office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures

performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the May 12, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

40. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]: Dr. Ellner coded the January 16, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. The office visit is directly related to the procedures performed, therefore, not separately reimbursable. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that he discussed the procedure specifically at this office visit.

41. Patient [redacted] (DOB [redacted] Medicare ID # [redacted]: Dr. Ellner coded the January 4, 2018 office visit as an established

office visit with CPT code 99213 with a 25 modifier. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

42. Patient [redacted] (DOB [redacted] Medicare ID # [redacted]: Dr. Ellner coded the January 4, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

43. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]: Dr. Ellner coded the December 7, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the

procedure specifically at this office visit. As referenced in the notes, the visit is even listed as "pre-procedural physical examination."

44. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]: Dr. Ellner coded the January 8, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

45. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]: Dr. Ellner coded the October 27, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. Dr. Ellner coded the January 10, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This visit should have been included in the procedure reimbursement. Dr. Ellner coded the April 6, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same days. The procedures were scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at these office visits.

46. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]: Dr. Ellner coded the August 18, 2017 office visit) as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

47. Patient [redacted] (DOB [redacted]; CAHABA GBA PART BID # [redacted]: Dr. Ellner coded the October 13, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

48. Patient [redacted] (DOB [redacted]; Palmetto GBA ID # [redacted]: Dr. Ellner coded the February 7, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the

procedure specifically at this office visit.

49. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]: Dr. Ellner coded the January 4, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. Dr. Ellner coded this note as an established office visit with CPT code 99213 with a 25 modifier.

50. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]: Dr. Ellner coded the September 22, 2015 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the December 4, 2015 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the March 17, 2016 office visit as an established office visit with CPT code 99213 with a 25

modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedures was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the August 11, 2016 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the December 16, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the May 11, 2017 office visit as an established office visit with CPT code 99214 with a 57 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

51. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Dr. Ellner coded the (January 9, 2017) office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the April 3, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the December 15, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

52. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Dr. Ellner coded the May 12, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. The procedure was scheduled in advance and listed

under "instructions" in the file note, which indicates that the doctor discussed the procedures specifically at this office visit. Dr. Ellner coded the June 5, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the October 11, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the November 7, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

53. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Dr. Ellner coded the September 15, 2015 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit

discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that he discussed the procedure specifically at this office visit. Dr. Ellner coded the December 11, 2015 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the March 3, 2016 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the June 1, 2016 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the October 19, 2016 office visit as an established office visit with CPT code

99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the January 10, 2017 office visit as an established office visit with CPT code 99213 with a 57 modifier (57 is used for pre-op or surgery same day for major surgery only—not the procedures Dr. Ellner performs). This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the June 26, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit. Dr. Ellner coded the September 14, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates

that Dr. Ellner discussed the procedure specifically at this office visit.

54. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): Dr. Ellner coded the December 4, 2017 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit.

55. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): Dr. Ellner coded the January 4, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit.

56. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): Dr. Ellner coded the December 1, 2017 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under

"instructions" in the file note, which indicates that Dr. Ellner discussed the procedure specifically at this office visit.

57. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Dr. Ellner coded the January 5, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the January 20, 2016 office visit as an established office visit with CPT code 99214 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the October 18, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. Dr. Ellner coded the November 9, 2016 office visit as an established office visit with CPT code 99213

with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note.

58. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): Dr. Ellner coded the January 26, 2016 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

59. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): Dr. Ellner coded the January 19, 2018 office visit as an established office visit with CPT code 99213 with a 25 modifier. This office visit discusses no new problems for this patient and is directly related to the procedures performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit. The 57 modifier was also inappropriately used on one of these claims. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note,

which indicates that the doctor discussed the procedure specifically at this office visit.

60. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Dr. Ellner coded the May 11, 2017 office visit as an established office visit with CPT code 99213 with a 57 modifier. The office visit discusses no new problems for this patient and is directly related to the procedure performed on the same day. The procedure was scheduled in advance and listed under "instructions" in the file note, which indicates that the doctor discussed the procedure specifically at this office visit.

III. GPM Upcoded Radiofrequency Ablations

61. Relator's foray into this subject started in the summer of 2017 when she spoke to Ms. Drago about GPM's practice of billing Radiofrequency Ablations (CPT codes 64633-64636) for the level and not the joint. Ms. Drago is the charge poster. Ms. Drago told Relator that Dr. Ellner knew he was billing it wrong, however, he wanted the extra money the incorrect billing provided him for these procedures. Dr. Ellner insisted that Ms. Drago post the charges by level and not by joint.

62. Local Coverage Determinations ("LCDs") governing billing for Radiofrequency Neurotomies (i.e., Radiofrequency Ablations; hereinafter: "RF Ablations") require that the provider bill according to the joint as opposed to the level. See Palmetto GBA, Local Coverage Determination (LCD): Facet Joint

Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. By way of explanation, each spinal vertebrae is classified as a level (i.e., L1, L2, L3, etc.), and levels are connected to one another via a facet joint. In requiring providers to bill according to the joint as opposed to the level, the LCDs sought to minimize the risk of providers overbilling for RF Ablations (e.g., billing for the joint between L3 and L4 instead of billing L3 and L4 separately). On numerous occasions, Relator conveyed to GPM clinicians and staff the proper way to code for RF Ablations. Despite this clear mandate and Relator's educational endeavors, GPM billed for RF Ablations by the level instead of by the joint so it could double bill for RF Ablations. To accomplish this feat, Dr. Ellner added an extra RF Ablation CPT Code (either CPT Code 64634 or 64636) to every claim in error.

63. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's RF Ablation should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates the "levels" were L3, L4, and L5. The billing was then submitted based on the "level" rather than the "joint" as 64635, 64636, and 64646/76. An extra "64636" was billed.

64. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on December 11, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. The billing for procedure on January 29, 2018 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

65. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were T12 and L1. The billing for the procedure on December 11, 2017 was submitted based on the "level" rather than the "joint." In addition, the patient had a procedure on January 25, 2018 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

66. Patient [redacted] (DOB [redacted]; Medicare ID [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L1, L2, and L3. The billing for the procedure on January 4, 2018 was submitted based on the level rather than the "joint" (L1-L2, L2-L3). In addition, the patient had a procedure on January 19, 2018 that should have been

coded as 64635 and 64636 only. Dr. Ellner added an extra code of 64636.

67. Patient [redacted] (DOB [redacted]; UHC Medicare # [redacted]): This patient had an RF Ablation that should have been coded as 64646 and 64635, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates the "levels" were L3, L4, and L5. The billing for the procedure on January 8, 2018 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

68. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on October 31, 2017 was submitted based on the "level" rather than the "joint." In addition, the patient had a procedure on December 18, 2017 that was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

69. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636. At the beginning of each operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on November 30, 2017 was submitted based on the level rather than the "joint." In addition, the patient had a procedure on December 18, 2017 that should have been coded as 64635

only. Dr. Ellner added an extra code of 64636.

70. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636. At the beginning of each operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on May 31, 2017 was submitted based on the "level" rather than the "joint." In addition, the patient had a procedure on December 7, 2017 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

71. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had an RF Ablation that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on December 22, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

72. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]): This patient had an RF Ablation that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on November 21, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

73. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]): This patient had an RF Ablation that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on April 6, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

74. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of each operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on January 8, 2018 was submitted based on the "level" rather than the joint. In addition, the patient had procedures on January 22, 2018 and January 29, 2018 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

75. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had an RF Ablation that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for this procedure on January 26, 2018 was then submitted based on the "level" rather than the "joint" as 64635, 64636.

76. Patient [redacted] (DOB [redacted]; Patient has Aetna [redacted]; Patient has Medicare [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. The billing for the procedure on November 10, 2015 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had procedures on December 8, 2015, October 26, 2017, and on November 20, 2017 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

77. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on August 19, 2015 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had procedures on September 4, 2015, May 9, 2016, June 14, 2016, and May 12, 2017 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

78. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for this procedure on January 18, 2018 was then submitted based on the "level" rather than

the "joint" as 64635 and 64636. In addition, the patient had a procedure on March 27, 2018 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

79. Patient [redacted] (DOB [redacted]; CAHABA GBA PART B ID # [redacted]): This patient had an RF Ablation that should have been coded by as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on November 21, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had procedures on December 7, 2017 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

80. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient had an RF Ablation that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that her "levels" were L2, L3, and L4. The billing for this procedure on January 4, 2016 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

81. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. The billing for this procedure on January

20, 2016 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had procedures on February 3, 2016 and November 9, 2016 that were then submitted based on the "level" rather than the "joint" as 64635 and 64636.

82. Patient [redacted] (DOB [redacted]; UHC # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure on April 3, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636.

83. Patient [redacted] (DOB [redacted]; UHC # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. The billing for the procedure on January 18, 2018 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had a procedure on January 29, 2018 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

84. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were L3, L4, and L5. The billing for the procedure

performed on January 10, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had procedures on September 14, 2017 that should have been coded as 64635 only. Dr. Ellner added an extra code of 64636.

85. Patient [redacted] (DOB [redacted]; UHC # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. The cervical RF Ablation performed on November 13, 2017 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. UHC Medicare requested medical records for this procedure. After they received the records, UHC Medicare determined that this procedure was over billed.

86. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had an RF Ablation that should have been coded as 64633 and 64636, which is by the joint. At the beginning of the operative report, Dr. Ellner indicates that the "levels" were C3, C4, and C5, which means that two levels are treated within a "joint" (C3-C4, C4-C5) not by the level (C3, C4, and C5).

87. Patient [redacted] (DOB [redacted]; UHC # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. The cervical RF Ablation performed on February 13, 2018 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. UHC Medicare requested medical records for this procedure.

After they received the records, UHC Medicare determined that this procedure was over billed. After review of the records, UHC Medicare reprocessed the claim and issued payment for only two procedure codes.

88. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had several RF Ablations that should have been coded as 64635 and 64636, which is by the joint. At the beginning of the operative reports, Dr. Ellner indicates the "levels" were L2, L3, and L4. The billing for the procedure on January 18, 2018 was then submitted based on the "level" rather than the "joint" as 64635 and 64636. The billing for the procedure on January 29, 2018 was also submitted based on the "level" rather than the "joint" as 64635 and 64636. In addition, the patient had a procedure on January 8, 2018 (lumbar medial branch block) that should have been coded as 64493/50 and 64494/50 only, but was billed with an extra code of 64495/50.

IV. GPM Upcoded Office Visits

89. Medicare will only pay for services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. §1395(a)(1)(A). The medical necessity requirement applies not only to the fact of treatment, but also to the level of treatment provided to the patient. For physician services, "medical necessity of a service is the overarching criterion" for determining which CPT code is appropriate. See CTRS. FOR MEDICARE & MEDICAID, MEDICARE CLAIMS PROCESSING

MANUAL, Chapter 12 § 30.6.1(A). Under the CPT coding system, the codes relating to physician visits and consultations are classified as Evaluation and Management ("E&M") services. New patient office visits are represented by CPT Codes 99201 to 99205. These five codes reflect a range of intensity of the services provided with the higher level codes indicating more intensive services. Accordingly, Medicare reimburses providers more for a higher level code (e.g., 99205) than a lower code (e.g., 99201). CMS has determined that "it would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted." *Id.* To avoid an improper selection, CMS instructs that physicians must "select the code for the service based upon the content of the service." *Id.* To determine the appropriate level of E&M services to be coded, seven components must be assessed. These components are: (1) patient history; (2) physical examination; (3) medical decision making; (4) counseling; (5) coordination of care; (6) the nature of the presenting problem; and (7) the time involved in meeting with the patient. The first three components of the assessment (patient history, physical examination, and medical decision making) are the most important elements for coding purposes. The greater the intensity of the history, examination, and medical decision making components, the higher the level of CPT E&M code that may be assigned.

90. GPM's physician-owner Dr. James Ellner failed to base his CPT code

selection for new office visits on the criteria specified by CMS. Instead, Dr. Ellner only billed new office visits under CPT 99204, regardless of the complexity and duration of the visit. Medicare Guidance stipulates that CPT Code 99204 should only be selected when there is a comprehensive patient history, a comprehensive physical examination, and moderate medical decision making involving multiple number of diagnosis or management options, moderate amount and/or complexity of data to be reviewed, and moderate risk of significant complications, morbidity, and/or mortality. Palmetto GBA, New Patient Office Visit (CPT Codes 99201-99205): Coverage and Documentation Requirements (last updated Feb. 07, 2018), *available at* https://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/JM%20Part%20B~eServices%20Portal~eCBR~New%20Patient%20Office%20Visit%20(CPT%20Codes%209920119205)%20Coverage%20and%20Documentation%20Requirements?open&Expand=1. Because of the intensity of services involved, these office visits typically last forty-five (45) minutes. Because Dr. Ellner uniformly selected CPT Code 99204 for all new patient visits instead of varying his selection according to the criteria espoused by CMS, claims submitted under CPT Code 99204 constitute medically unnecessary services, and are therefore not entitled to reimbursement from federal payors.

91. Relator expressed her discontent for these practices with, Becky Barnhill, the office administrator. Ms. Barnhill responded by saying "well, that's

the code we use for all new patient office visits." When Relator informed her that each visit varies by complexity and duration, Ms. Barnhill stuck with her original statement that Dr. Ellner only uses CPT 99204 regardless of the complexity of the visit or whether he spends 10 minutes or one hour with the patient, he always uses the same new patient E&M CPT code. Dr. Ellner submitted a false E&M code for the following patients:

92. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]).

93. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]).

94. Patient [redacted] (DOB [redacted]; CAHABA Medicare ID # [redacted]).

95. Patient [redacted] (DOB [redacted]; CAHABA Medicare ID # [redacted]).

96. Patient [redacted] (DOB [redacted]; CAHABA Medicare ID # [redacted]).

97. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]).

98. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]).

99. Patient [redacted] (DOB [redacted]); CAHABA #

[redacted]).

V. GPM Intentionally Falsifies Its Claim Submissions to Include Inappropriate Diagnosis Codes

100. To participate in the Medicare Program, physicians must submit a Medicare Enrollment Application, Form CMS-855I. Medicare regulations require providers and suppliers to certify that they will meet the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1). When a physician signs the certification statement contained in Form CMS-855I, he attests that "[he] will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and [he] will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." See Form CMS-855I. As discussed, *inter alia*, physicians seeking reimbursement for services rendered to Medicare beneficiaries submit a claim to the Medicare carrier on a Form CMS-1500. The claim details the five-digit CPT Code identifying the services or procedures performed on the beneficiary. To qualify for reimbursement, the CPT Code must be supported by a separate diagnosis code from the International Classification of Diseases, Tenth Revision, Clinical Modification/Procedure Coding System ("ICD-10-CM/PCS," hereinafter: "ICD-10"). Prior to October 15, 2015, diagnosis codes were classified according to the ICD-9-CM. When filing the electronic equivalent of Form CMS-1500, a provider certifies that ". . . the services shown on this form were medically indicated and necessary for the health of the patient and were

personally furnished by me or were furnished incident to my professional service by my employee under my immediate supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations." See Form CMS-1500.

101. As a physician participant in the Medicare Program, Dr. Ellner executed and submitted a Form CMS-855I and certified he would not submit claims with deliberate ignorance or reckless disregard of their falsity. Moreover, for all claims submitted on a Form CMS-1500, Dr. Ellner certified that the services shown were medically indicated, necessary for the health of the patient, and personally performed by him or a qualified member of his staff. On numerous occasions, Dr. Ellner false diagnosis codes on claims, thereby violating the certifications enumerated in both the Form CMS-855I and the Form CMS-1500. Specifically, Dr. Ellner would depart from the diagnosis he documented in his medical office notes and impute a different diagnosis code on the Form CMS-1500. By changing the diagnosis code, Dr. Ellner could receive reimbursement for a CPT code that would have been unsupported by the diagnosis code in his medical office notes. Relator apprised GPM clinicians to the National Coding Determinations ("NCDs") and Local Coverage Determinations ("LCDs"), which detail the required timelines, acceptable diagnosis codes and/or conditions, and the medical necessity criteria for various procedures. Instead of using this knowledge to achieve compliant billing, Dr. Ellner used it to obtain reimbursement for services to which he was not entitled.

Some examples follow:

102. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. There cannot be a presence of radiculopathy when performing the procedures. In the office visit note, Dr. Ellner uses diagnosis code "M47.816" listed under "Assessment," which is spondylosis of the lumbar region without myelopathy or radiculopathy. This diagnosis does not match the description of symptoms on this very same progress note as radiculopathy was indicated in the beginning of the office visit note when it is states "The pain radiates to right knee and shin." Anytime that there is radiation of pain from the spine, it is considered "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.816. The procedure note indicates "minimal radiation," which is a contraindication for facet joint injections per Medicare and does not support diagnosis code M47.816 used since this diagnosis states that radiculopathy cannot be present.

103. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. Radiculopathy is indicated by stating that there is "minimal radiation" in the operative report. On the operative report, "minimal radiation" is indicated, which is a contraindication for facet joint injections per

Medicare and does not support the diagnosis code M47.816. ICD-10 code M47.816 is Spondylosis without myelopathy or radiculopathy.

104. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): GPM applied false diagnosis codes to records so that this procedure could be performed. The operative report uses diagnosis code "M54.16" listed under "Assessment," which is lumbar radiculopathy. This diagnosis clearly does not match the progress note that states [redacted] has no radiating pain.

105. Patient [redacted] (DOB [redacted]; Medicare ID [redacted]): GPM applied false diagnosis codes to this patient's records so that procedures could be performed. There cannot be a presence of radiculopathy when performing these procedures. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which is spondylosis of the cervical region without myelopathy or radiculopathy. This assessment does not support the radiculopathy suggested in the notes. In fact, non-radicular pain is never introduced when describing the patient's pain. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated "The pain radiates to bilateral shoulders." Any time that there is radiation of pain, it is called "radiculopathy."

106. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that

the procedure could be performed. There cannot be a presence of radiculopathy when performing this procedure. The procedure uses diagnosis code "M47.816" listed under "Assessment," which is spondylosis of the lumbar region without myelopathy or radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to bilateral buttocks and lower legs." Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.816. The procedure note indicates "minimal radiation," which is a contraindication for facet joint injections per Medicare and does not support diagnosis code M47.816 used since this diagnosis states that radiculopathy cannot be present.

107. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. There cannot be a presence of radiculopathy when performing the procedures. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which is spondylosis of the cervical region without myelopathy or radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to left bilateral shoulder." Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when

using diagnosis code M47.812.

108. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. There cannot be a presence of radiculopathy when performing these procedures. Dr. Ellner uses diagnosis code "M47.817" listed under "Assessment," which is spondylosis of the lumbar region without myelopathy or radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated that the pain radiates to buttocks, hip, thigh, and hamstring. Lumbar radiculitis is actually assigned to one of the office notes. Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.817.

109. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM applied false diagnosis codes to the patient's records so that the facet joint injection could be performed. There cannot be a presence of radiculopathy when performing this procedure. In the operative report, Dr. Ellner uses diagnosis code "M47.816" listed under "Assessment," which is spondylosis of the cervical region without myelopathy or radiculopathy. This assessment does not support the radiculopathy suggested in the notes. In fact, non-radicular pain is never introduced when describing the patient's pain. This diagnosis clearly does not match the

progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to bilateral buttocks, hip, and thigh." Radiculopathy was also listed under assessment on the progress note. Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.816.

110. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedure could be performed. There cannot be a presence of radiculopathy when performing this procedure. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which is spondylosis of the cervical region without myelopathy or radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to left shoulder and occipital." Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.812.

111. Patient [redacted] (DOB [redacted]; Medicare # [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. There cannot be a presence of radiculopathy when performing these procedures. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which is spondylosis of the cervical region without myelopathy or

radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to bilateral shoulders and left occipital." Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.812.

112. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): GPM applied false diagnosis codes to the patient's records so that the procedure on could be performed. There cannot be a presence of radiculopathy when performing this procedure. Dr. Ellner uses diagnosis code "M47.816" listed under "Assessment," which is spondylosis of the lumbar region without myelopathy or radiculopathy. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note when it is stated, "The pain radiates to right thigh, hamstring, knee, and foot." Any time that there is radiation of pain, it is called "radiculopathy." Radiculopathy cannot be present when using diagnosis code M47.816.

113. Patient [redacted] (DOB [redacted]; Patient has Aetna [redacted]; Patient has Medicare [redacted]): GPM applied false diagnosis codes to the patient's records so that procedures could be performed. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which does not support the radiculopathy suggested in the notes. This diagnosis clearly does not match the

progress note as radiculopathy is clearly indicated. There cannot be a presence of radiculopathy when performing this procedure.

114. Patient [redacted] (DOB [redacted]; Palmetto GBA # [redacted]): GPM applied false diagnosis codes to the patient's records so that the procedure could be performed. Dr. Ellner uses diagnosis code "M47.812" listed under "Assessment," which does not support the radiculopathy suggested in the notes. This diagnosis clearly does not match the progress note as radiculopathy was clearly indicated in the beginning of the office visit note. Radiculopathy cannot be present when using diagnosis code M47.812.

VI. Falsification of Patient Records

115. Physicians submitting a Form CMS-855I must certify that "[he will not present or cause to be presented a false or fraudulent claim for payment by Medicare, and [he] will not submit claims with deliberate ignorance or reckless disregard for their truth or falsity." See Form CMS-855I. Medicare covers–and participating providers agree to submit claims only for–services that are medically necessary to diagnose and treat illness or injury, and for which the provider maintains adequate supporting documentation corroborating the treatment administered and for which reimbursement is sought. 42 U.S.C. § 1395(y)(a)(1)A). CMS establishes its national payment policy for items or services covered by Medicare through binding NCDs, which are formal decisions indicating whether, and under what

circumstances, Medicare covers a particular item or service. 42 U.S.C. §1395ff(f)(1); 42 C.F.R. §495.1060(a). In addition, Medicare contractors–those entities that contract with CMS to review and pay claims submitted by health care providers–issue LCDs for their specific jurisdiction. See 42 U.S.C. §1395ff(f)(2).

116. On numerous occasions, Dr. Ellner–working in concert with Donna Drago–falsified patient symptoms in his office visit notes so the notes would conform with the coverage requirements for various procedures enumerated in NCDs and LCDs. Dr. Ellner would see a patient and record the patient's symptoms. He would then make a recommendation for a procedure. After Dr. Ellner finalized his notes, Ms. Drago would print out a copy and make redline edits indicating what sections needed to be removed or adjusted so the symptoms mirrored those required by NCDs and LCDs for the recommended procedure. In addition, Ms. Drago would indicate patient symptoms Dr. Ellner should embellish so GPM could perform and bill for additional procedures. Dr. Ellner would then make the edits in the patient notes. Some examples follow:

117. Patient [redacted] (DOB [redacted]): In a redline, Donna Drago indicated that Dr. Ellner needed to change "non-radicular" pain so that either a medial branch block ("MBB"), facet joint injection, or RF Ablation could be performed. In order to perform these procedures, the patient must have had non-radicular pain for at least 3 months. As noted in the redline, the patient indicated

radicular pain: "The pain radiates to bilateral occipital, and left shoulder." Dr. Ellner then falsified this medical records to state that the patient did not have radicular pain. Ms. Drago also suggested that Dr. Ellner change the percentage of relief so that he could do a third injection on the very same day. Ms. Drago wrote: "She is scheduled for 3rd TF in Samson today." Per Medicare guidelines, the patient must have at least 50% relief from the previous transforaminal injection to perform a repeat transforaminal injection. Then, Ms. Drago crossed out that Dr. Ellner discussed the TF procedure to be performed the same day and asked him to remove his note of "I have discussed a bilateral L5 transforaminal epidural steroid injection under fluoroscopy; the patient wishes to procedure with the procedure." Having this statement on the office visit note indicates that Dr. Ellner discussed the procedure specifically at the patient's office visit. Ms. Drago does not want Dr. Ellner to include this so he could bill for the office visit separately. Dr. Ellner makes Ms. Drago's changes and either makes a check mark or X on the note and gives it back to Ms. Drago. The marks from him indicate that he made these changes and the note has been changed.

118. Patient [redacted] (DOB [redacted]). On a redline, Donna Drago crossed out and instructed Dr. Ellner to remove his note of "I have discussed a left C2-4 MBB under fluoroscopy; the patient wishes to proceed with the procedure. If patient receives the expected relief, the patient will be scheduled

for an RF Ablation." Having this statement on the office visit note indicates that Dr. Ellner discussed the procedure specifically at this office visit. Ms. Drago was concerned with this note and billing for this office visit separately. Ms. Drago also crossed out "I recommend the patient proceeds with a radio frequency ablation." Dr. Ellner technically cannot recommend the RF Ablation until two MBBs have been performed. Dr. Ellner makes Ms. Drago's changes and either makes a check mark or X on the note and gave it back to Ms. Drago. The marks from him indicate that he made these changes and the note has been changed.

119. Patient [redacted] (DOB [redacted]): On a redline, Donna Drago wrote in red ink "see last page." Ms. Drago then crossed out Dr. Ellner's notes of "I have discussed a bilateral L5 transforaminal epidural steroid injection under fluoroscopy; the patient wishes to procedure with the procedure." Having this statement on the office visit note indicates that Dr. Ellner discussed the procedure specifically at this office visit. Ms. Drago was concerned with this note and billing for this office visit separately. Ms. Drago even reminded Dr. Ellner that the patient was "scheduled for a TF in Samson today" in red ink.

120. Patient [redacted] (DOB [redacted]): Donna Drago marked the patient records with a Red "X" on "radiates" and made a note to Dr. Ellner to change to "does not radiate." Ms. Drago wanted him to change this to "non-radicular" pain so that either a MBB, facet joint injection, or RF Ablation could

be performed. In order to perform these procedures, the patient must have non-radicular pain for at least 3 months. In the notes, the patient indicated radicular pain: "The pain radiates to right buttocks, hip, thigh, and hamstring." Dr. Ellner then false these medical records to state that the patient did not have radicular pain.

121. Patient [redacted] (DOB [redacted]): On a redline, Donna Drago wrote in red ink "not a procedure follow-up appointment as stated within the note it is too soon to evaluate % of relief from procedure." She wanted Dr. Ellner to remove "follow up from procedure," (as circled in red) listed under History & Physical as a reason for his visit. Ms. Drago wanted Dr. Ellner then to add that this was a medication management visit. The office visit may have fallen within the global timeframe because it was a follow up on a procedure. Therefore, Ms. Drago wanted the visit to be focused on something else in order to bill it separately. Ms. Drago also underlined the percentage sentence indicating to Dr. Ellner that he needed to remove this information. Ms. Drago revised Dr. Ellner's office visit notes to create medical necessity for procedures fraudulently. Dr. Ellner then went back and made these changes and either made a check mark or an X on the note and gave it back to Ms. Drago. The marks from him indicate that he made these changes and the note has been changed.

VII. Labs

122. GPM has historically engaged in inappropriate and illegal behavior with various laboratories, including Genotox Laboratories, Ltd. ("Genotox") and Aegis Sciences Corporation ("Aegis"). Primarily, it involves the lab providing a free employee to GPM and then assisting GPM in falsely billing for Urinary Drug Screens ("UDS"). In the case of GPM, the labs do not just provide any free employee as a kickback, but GPM insists that if the lab wants all GPM's business, it must provide (and pay for) Angela Humphrey. The current lab with this arrangement is Aegis. Prior to working for Aegis, Angela Humphrey worked for Genotox and performed the same duties that she does now for the GPM office. Dr. Ellner told Aegis that he would only change labs to Aegis if they hired Angela Humphrey and paid her to perform the same duties that she was performing for GPM at that time. The "deal" included Angela Humphrey performing duties that should have been (and normally would have been) performed by GPM staff—not the lab. These included, *inter alia*, reviewing the GPM patient schedule, ordering UDSs for patients ahead of the doctor's visit, collecting the urine samples, and scanning in the results to the EMR.

123. The UDSs are being performed before the physician even sees the patient or orders the lab. Angela Humphrey (Aegis Employee) has access to Defendants' schedule and patient charts in Greenway (EMR). Ms. Humphrey pulls

the schedule the day before patients come in and goes through the charts to determine if she wants to order a UDS for the patient. Ms. Humphrey automatically performs the drug screens on patients who have not had a drug screen in a couple of months.

124. Because GPM does nothing except refer laboratory work, it should not bill anything with regard to the labs. However, given the kickback relationship, GPM is allowed to bill the lab work and kick back part of the bill to the lab. One time this got crossed up and there was quite the dustup. In late 2017 and early 2018, GPM billed for the UDS which was considered preliminary (run through the analyzer) on certain patients. However, Genotox had already billed for the patients. Since GPM was behind on posting charges, it did not know Genotox had been billing the clients until months later. Relator called Medicare to find out why the claims were being rejected as "duplicate," and was told that Genotox had billed and been paid for the screens. Relator informed Becky Barnhill. Dr. Ellner and Ms. Barnhill were very angry and went back and forth on phone calls with Genotox management. Genotox's proposal was to simply write a check to Dr. Ellner for all of the labs that they had been paid for with the "80307" code. Relator informed Ms. Barnhill that absolutely under no circumstances should they accept this payment. Relator told Ms. Barnhill that the only correct way to do this was if Genotox refunded Medicare directly for these and then GPM appealed the denial to Medicare. This was not acceptable to Dr. Ellner and he discussed it several times

with Ms. Barnhill. On several occasions, Relator insisted that they not do it the way Genotox offered. Eventually, Genotox issued a full refund to Medicare, and GPM appealed each one. It is possible that GPM asked Genotox to sweeten the pot "for their troubles," as Ms. Barnhill and Dr. Ellner indicated that they thought they deserved something from Genotox for "the trouble." Relator is unaware if anything else changed hands.

A. Dr. Ellner Did Not Order Urinary Drug Screens–Orders Were Created by Lab Employees

125. The Social Security Act requires that all claims submitted for reimbursement be "medically necessary." Pursuant to its rulemaking authority under the Social Security Act, CMS has promulgated regulations defining when a medical procedure fails to qualify as medically necessary. These regulations encompass diagnostic tests, such as a urinary drug screenings ("UDS"). The regulations governing diagnostic tests mandate that only the treating physician or a non-physician practitioner (defined as, a "clinical nurse, specialist, clinical psychologist, clinical social worker, nurse-midwife, nurse practitioner, [or] physician assistant") may place the order. 42 C.F.R. § 410.32(a). GPM's practice of allowing Angela Humphrey—a lab technician—to order UDS for GPM patients violates this regulation, thereby rendering the claim medically unnecessary, and disqualified from reimbursement. Some examples follow:

126. Patient [redacted] (DOB [redacted]; UHC # [redacted]):

A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

127. Patient [redacted] (DOB [redacted]; Piedmont WellStar Medicare Choice # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

128. Patient [redacted] (DOB [redacted]; TRICARE # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

129. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

130. Patient [redacted] (DOB [redacted]; UHC # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

131. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

132. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

133. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

134. Patient [redacted] (DOB [redacted]; CAHABA #

[redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

135. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

136. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

137. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

138. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

139. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

140. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

141. Patient [redacted] (DOB [redacted]; Cigna Medicare ID # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

142. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

143. Patient [redacted] (DOB [redacted]; Humana # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

144. Patient [redacted] (DOB [redacted]; CAHABA #

[redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

145. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

146. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

147. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

148. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

149. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

150. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

151. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

152. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

153. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

154. Patient [redacted] (DOB [redacted]; UHC # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

155. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

156. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

157. Patient [redacted] (DOB [redacted]; UHC # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

158. Patient [redacted] (DOB [redacted]; Humana # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

159. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

160. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

161. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

162. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

163. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

164. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDS for this patient.

165. Patient [redacted] (DOB [redacted]; CAHABA # [redacted]): A lab worker, rather than Dr. Ellner, ordered the UDSs for this patient.

B. Failure to Perform Clinical Assessment Renders Urinary Drug Screen Medically Unnecessary

166. CMS regulations mandate that all orders for UDS be supported by a clinical assessment documented in the patient's medical record. 42 C.F.R. § 410.32(2); Ctrs. for Medicare & Medicaid Servs., ICN 909412, Provider Compliance Tips for Laboratory Tests–Other—Urine Drug Screening (2016). Failure to do so renders the claim medically unnecessary, and therefore disqualifies the claim for reimbursement. CMS regulations also require that the treating physician or qualified nonphysician practitioner who orders a UDS maintain proper documentation of medical necessity in the beneficiary's medical record. 42 C.F.R. § 410.32. Without the documentation of the assessment and the justification for ordering UDS, it is unnecessary and no reimbursement is allowed.

167. GPM had three protocols that violate these requirements. First, UDSs were run before or without a clinical assessment. Second, no clinical assessment was recorded in the patient's file. Third, UDSs were scheduled based on a routine screening rather than a clinical assessment. In fact, Dr. Ellner uses a flag on the

charts of the patients to remind the lab tech to set up a UDS every three months regardless of necessity. This "flag" shows on the patient chart reading "3 Month Meds/USD Everytime." A copy of the flag pops up on the patients chart in the EMR every time the lab tech opens the file. In fact, Angela Humphrey—an unlicensed lab technician—orders UDS for all GPM patients prior to any clinical assessment, without any clinical assessment, and/or based only on a routine screening procedure. This constitutes a clear violation of this regulatory mandate.

1. UDS were run before a clinical assessment

168. This list will show the copy of the schedule showing the appointment time on the schedule (A) and then the UDS document showing urine "collection time" at the very beginning of the appointment time (B). This is documented proof that the patient's urine was collected prior to being seen by the physician. The physician would have needed to include specific clinical documentation as to why the UDS is being ordered prior to the urine being collected. The average time that the patients waited before seeing the physician was 30-60 minutes after their actual appointment time, therefore, the urine was collected long before the physician ever saw the patient. Moreover, Dr. Ellner often did not arrive to the office until 8:30-8:45 a.m. even though his schedule usually started at 8:00 a.m.

169. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr.

Ellner. GPM's daily schedule report shows the patient had an appointment at 1:30 p.m. on April 17, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:30 p.m. on April 17, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

170. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 1:45 p.m. on April 17, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:45 p.m. on April 17, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

171. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:15 p.m. on April 17, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:15 p.m. on April 17, 2017, or prior to

the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

172. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 8:30 a.m. on April 18, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 8:30 a.m. on April 18, 2018, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

173. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 10:00 a.m. on April 18, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 10:00 a.m. on April 18, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

174. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr.

Ellner. GPM's daily schedule report shows the patient had an appointment at 11:45 a.m. on April 18, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 11:45 a.m. on April 18, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

175. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 12:45 p.m. on April 18, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 12:45 p.m. on April 18, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

176. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 3:15 p.m. on April 18, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 3:15 p.m. on April 18, 2017, or prior

to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

177. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 11:00 a.m. on April 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 11:00 a.m. on April 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

178. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 12:45 p.m. on April 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 12:45 p.m. on April 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

179. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr.

Ellner. GPM's daily schedule report shows the patient had an appointment at 1:45 p.m. on April 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:45 p.m. on April 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

180. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 3:45 p.m. on April 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 3:45 p.m. on April 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

181. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 9:30 a.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 9:30 a.m. on April 21, 2017, or prior to

the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

182. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 1:30 p.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:30 p.m. on April 21, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

183. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:00 p.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:00 p.m. on April 21, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

184. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr.

Ellner. GPM's daily schedule report shows the patient had an appointment at 2:15 p.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:15 p.m. on April 21, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

185. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:15 p.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:15 p.m. on April 21, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

186. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:45 p.m. on April 21, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:45 p.m. on April 21, 2017, or prior to

the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

187. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 12:45 p.m. on June 19, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 12:45 p.m. on June 19, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

188. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 12:45 p.m. on June 19, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 12:45 p.m. on June 19, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

189. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr.

Ellner. GPM's daily schedule report shows the patient had an appointment at 1:15 p.m. on June 19, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:15 p.m. on June 19, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

190. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 1:30 p.m. on June 19, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 1:30 p.m. on June 19, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

191. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 3:00 p.m. on June 19, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 3:00 p.m. on June 19, 2017, or prior to the

patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

192. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:30 p.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:30 p.m. on June 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

193. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:45 p.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:45 p.m. on June 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

194. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's

daily schedule report shows the patient had an appointment at 8:45 a.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 8:45 a.m. on June 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

195. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 11:15 a.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 11:15 a.m. on June 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

196. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 11:30 a.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 11:30 a.m. on June 20, 2017, or prior to

the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

197. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's urine sample was taken prior to the patient seeing Dr. Ellner. GPM's daily schedule report shows the patient had an appointment at 2:00 p.m. on June 20, 2017. The standard wait time to see the doctor is 30-60 minutes, with the doctor typically arriving at the office around 8:30-8:45 a.m. The UDS document shows the collection time to be 2:00 p.m. on June 20, 2017, or prior to the patient seeing the doctor and, thus, the doctor could not have run a clinical assessment prior to the UDS.

2. No clinical assessment was recorded in the patient's file

198. Patient [redacted] (DOB [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

199. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

200. Patient [redacted] (DOB [redacted]; UHC ID #

[redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

201. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

202. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

203. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

204. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

205. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

206. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the dates of service that UDSs were performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

207. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

208. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

209. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

210. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

211. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

212. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

213. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

214. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

215. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

216. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

217. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

218. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

219. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

220. Patient [redacted] (DOB [redacted]; Humana ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

221. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

222. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

223. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

224. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

225. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

226. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

227. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

228. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

229. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

230. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

231. Patient [redacted] (DOB [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

232. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

233. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

234. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

235. Patient [redacted] (DOB [redacted]; UHC ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

236. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

237. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

238. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

239. Patient [redacted] (DOB [redacted]; CIGNA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

240. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

241. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

242. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

243. Patient [redacted] (DOB [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

244. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

245. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

246. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office notes for the date of service that a UDS was performed do not contain any indication that a clinical assessment was made or provide any justification for a screen or any clinically supportive documentation.

3. UDS were scheduled based on a routine screening rather than a clinical assessment

247. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): Dr. Ellner used a flag on the patient's chart. It tells the staff to automatically collect urine for this patient at every visit, which is usually around every three months.

248. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): Dr. Ellner used a flag on the patient's chart. It tells the staff to automatically collect urine for this patient at every visit, which is usually around every three months.

249. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Dr. Ellner used a flag on the patient's chart. It tells the staff to automatically collect urine for this patient at every visit, which is usually around every three months.

C. GPM Is Not Allowed To Submit Urinary Drug Screen Claims Because It Does No Work

250. CMS has determined that only independent clinical laboratories may bill for referred laboratory services. CMS Pub. 100-04, chp. 16, sec. 40.1.1. An independent clinical laboratory is one that is "independent of an attending or consulting physician's office." *Id.* at sec. 10.1. As such, physicians may not submit claims for referred laboratory services on behalf of an independent clinical laboratory. Palmetto GBA, CPT Modifier 90 (last updated Feb. 15, 2018), *available at* https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Railroad-Medicare~8EEL9K2621. GPM does not qualify as an independent clinical laboratory because it is not independent of its sole treating physician, Dr. James Ellner. There is also no supervision by Dr. James Ellner or any participation of anyone in the practice. All of GPM's laboratory services were performed either by Angela Humphrey—an Aegis lab technician—or Aegis personnel at Aegis's laboratory facility. To make it appear as though GPM staff had performed the laboratory services that were in fact referred out to Aegis (or other labs), GPM falsified its order forms to state that GPM staff collected urine samples. A comparison of the collectors' signatures on GPM's "pre-signed" forms and Aegis Laboratory Request forms illustrates this discrepancy. These fraudulent documents were material to a false claim and were made by GPM, used by GPM, and caused to be made by Dr. Ellner.

251. Defendants knew that what they were doing was wrong. For example, early on in Relator's tenure, there were several insurance companies asking for supporting records for UDS claims. Relator had just mailed off office visit notes and all lab paperwork when she mentioned it to Donna Drago. Ms. Drago excitedly said "Don't send them ALL of the lab paperwork ever!" Relator later understood the urgent and exclamatory nature of this command when she found out that GPM was falsely certifying that Ms. Debra Stregowski was collecting. Other lab paperwork showed that Ms. Humphrey was the only one collecting samples and the calendar at work showed that Ms. Stregowski was on vacation or otherwise not in the office on many dates she certified that she collected the samples.

252. Debra Stregowski never collected urine samples nor ran them through the analyzer. She never had anything to do with the urine cups at all. Her job duties do not include the urine collection. However, she "pre-signed" a form certifying that she collected urine, and Angela Humphrey added the date of collection to that copied certification paper. Ms. Stregowski's signature is exactly the same for every patient's labs in the office.

1. GPM falsely certifies that someone from its office collects the samples as shown on order form

253. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms.

Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

254. Patient [redacted] (DOB [redacted]; Piedmont WellStar Medicare Choice ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

255. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she collected the urine (not Debra Stregowski).

256. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine

(not Debra Stregowski).

257. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

258. Patient [redacted] (DOB [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

259. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she collected the urine (not Debra Stregowski).

260. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra

Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

261. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

262. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

263. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed

her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

264. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

265. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

266. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

267. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

268. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

269. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

270. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra

Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

271. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

272. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

273. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed

her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

274. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

275. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

276. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

277. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

278. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

279. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

280. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra

Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

281. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

282. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

283. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed

her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

284. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

285. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

286. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

287. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

288. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

289. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

290. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra

Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

291. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

292. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

293. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH"

to the lab order indicating that she actually collected the urine (not Debra Stregowski).

294. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

295. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

296. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski).

2. GPM falsely certifies that someone from its office collects the samples as shown on schedule

297. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski). Furthermore, Debra Stregowski was out of town on the date of service as referenced on the schedule.

298. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski). Furthermore, Debra Stregowski was out of town on the date of service as referenced on the schedule.

299. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine

(not Debra Stregowski). Furthermore, Debra Stregowski was out of town on the date of service as referenced on the schedule.

300. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Angela Humphrey later signed her initials "AMH" to the lab order indicating that she actually collected the urine (not Debra Stregowski). Furthermore, Debra Stregowski was out of town on the date of service as referenced on the schedule.

301. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

302. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

303. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

304. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

305. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

306. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

307. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx

ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

308. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

309. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

310. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

311. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

312. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

313. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

314. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

315. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

316. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

317. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

318. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

319. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

320. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

321. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

322. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

323. Patient [redacted] (DOB [redacted]; UHC ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

324. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

325. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

326. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

327. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

328. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

329. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

330. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" forms. Debra Stregowski was out of town on the date of service as referenced on the schedule.

331. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): GPM created a false certification making it appear that Debra Stregowski collected the patient's urine sample by photocopying pre-signed forms. Angela Humphrey filled in the "pre-signed" form. Debra Stregowski was out of town on the date of service as referenced on the schedule.

3. Lab employee puts all information into EMR

332. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

333. Patient [redacted] (DOB [redacted]; Piedmont WellStar Medicare Choice ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

334. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

335. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR

336. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

337. Patient [redacted] (DOB [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

338. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

339. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

340. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

341. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

342. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

343. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

344. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

345. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

346. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

347. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

348. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

349. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

350. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

351. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

352. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

353. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

354. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

355. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

356. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

357. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

358. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

359. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

360. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

361. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

362. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

363. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

364. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

365. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

366. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

367. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

368. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

369. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

370. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

371. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

372. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

373. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

374. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

375. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Angela Humphrey scanned in the results of the UDS to the EMR.

4. Lab employee runs analysis

376. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

377. Patient [redacted] (DOB [redacted]; Piedmont WellStar Medicare Choice ID # [redacted]): Aegis employee, Joe (LNU), comes in every

few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

378. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

379. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

380. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

381. Patient [redacted] (DOB [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

382. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

383. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

384. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

385. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

386. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

387. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

388. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

389. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

390. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine

through the analyzer. Then lab employees send the urine sample off for final results.

391. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

392. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

393. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

394. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

395. Patient [redacted] (DOB [redacted]; Cigna Medicare Rx ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

396. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

397. Patient [redacted] (DOB [redacted]; Humana ID #

[redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

398. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

399. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

400. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

401. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

402. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

403. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

404. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

405. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

406. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

407. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

408. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

409. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

410. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine

through the analyzer. Then lab employees send the urine sample off for final results.

411. Patient [redacted] (DOB [redacted]; Aetna ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

412. Patient [redacted] (DOB [redacted]; Humana ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

413. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

414. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

415. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

416. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

417. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

418. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Aegis employee, Joe (LNU), comes in every few days to run urine through the analyzer. Then lab employees send the urine sample off for final results.

5. The lab and billing arrangements constitute stark and AKS violations

419. The Medicare and Medicaid Fraud and Abuse Statute (AKS), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1977. The AKS prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute ascribes liability to both sides of an impermissible kickback relationship.

420. The splitting of the billing for lab work when GPM does none of the work and is only getting to bill in exchange for exclusive referrals to Aegis (and previously Genotox) is a violation of the AKS. Aegis's and Genotox's provision of Angela Humphrey to GPM to perform office and medical tasks also constitutes a violation of the AKS. The OIG has specifically stated numerous times that the provision of free services to an actual or potential referral source can constitute prohibited remuneration under the federal AKS, particularly where the tasks involve

those normally performed by the physician's office staff. See Dep't of Health & Human Servs. Office of Inspector Gen., Opinion Letter on Free Services Performed by Clinical Laboratories (Oct. 2, 1997), *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/freelabs100297.htm. Here, GPM has received this exact prohibited remuneration in exchange for referrals for comprehensive urinalysis, thus giving rise to an AKS violation.

421. The Stark Law imposes civil liability on physicians who refer designated health services ("DHS"), including urinary drug screens, to any entity furnishing DHS in which the physician has a financial relationship. 42 U.S.C. § 1395nn. Financial relationships include "compensation arrangements," which comprise "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. §§ 1395nn(h)(1)(A), 1395nn(h)(1)(C). Because the office and medical tasks performed by Angela Humphrey represent a benefit to GPM (as GPM does not have to expend monies on a salary for an additional staff member), a compensation arrangement exists between GPM and Aegis and Genotox. Also, the ability to bill for work that is not performed by GPM is remuneration for referrals and "compensation" to GPM. Therefore, because a compensation arrangements exists between a DHS entity (Aegis and Genotox) and a physician (Dr. James Ellner), and Dr. Ellner refers DHS (urine samples for, confirmatory urinalysis) paid for by Medicare, these referrals and the ensuing

payments made by Medicare are tainted by Stark Law violations.

VIII. GPM Billed For Improper And Unnecessary Procedures

A. Facet Joint Injections

422. Facet joint injections are techniques used in the diagnosis and/or treatment of chronic neck and back pain. See Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The procedure involves injecting a mixture of anesthetic and anti-inflammatory medication directly into the facet joint space. Ray M. Baker, *Facet Joint Injection Procedure*, SPINE-HEALTH (last updated Mar. 22, 2013), https://www.spine-health.com/treatment/injections/facet-joint-injection-procedure.

1. Contraindication radiculopathy

423. Palmetto GBA has listed as one of the indications for a facet joint injection that the patient must present with pain that is "predominantly axial . . . [and] not associated with radiculopathy." Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. Radiculopathy is defined as "any disease of the spinal

nerve roots and spinal nerves . . . characterized by pain that seems to radiate from the spine, extending outward to cause symptoms away from the source of the spinal nerve root irritation." *Medical Definition of Radiculopathy*, MedicineNet.com (last editorial review May 13, 2016), https://www.medicinenet.com/script/main/art.asp?articlekey=14161. As such, if a patient presents with pain that radiates from a portion of the spine, radiculopathy is present. Because the clinical efficacy and utility of facet joint injections remains undocumented in the medical literature, Palmetto GBA only provides coverage for the procedure when the pain reported by the patient is concentrated around the facet joint (i.e., non-radicular). Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471.

424. Despite this clear guidance, GPM continued to order and bill for facet joint injections when patients presented with radiculopathy. Because the LCDs list radiculopathy as a contraindication, none of these facet joint injections qualify as medically necessary. As such, they are not entitled to reimbursement.

425. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office notes state that this patient has low back pain that radiates from his right hip, thigh, and knee (i.e., radiculopathy). The patient's notes assign

lumbar radiculopathy as one of the assessed diagnosis codes listed under "Assessment." Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations on this patient.

426. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office note states that this patient has low back pain that radiates from her low back to her buttocks and lower legs (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed a facet joint injection.

427. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office visit notes state that this patient has neck pain that radiates to his left shoulder (i.e., radiculopathy). The patient notes assign facet joint injections with the presence of radiculopathy. Even though the patient did not qualify, Dr. Ellner performed a facet joint injection.

428. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office visit notes state that this patient has neck pain that radiates to his left shoulder (i.e., radiculopathy) as well as low back pain that radiates to her buttocks, hip, thigh, hamstring, calf, and foot. Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations.

429. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The office visit note states that this patient has low back pain that radiates to his bilateral buttocks, hip, and thigh (i.e., radiculopathy). Even though the patient did

not qualify, Dr. Ellner performed facet joint injections.

430. Patient [redacted] (DOB [redacted]; UHCID # [redacted]): The office visit notes state that the patient has low back pain that radiates to his bilateral buttocks, hip, thigh, and knee (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections.

431. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office visit notes state that the patient has neck pain that radiates to her bilateral shoulders and left occipital (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations on this patient.

432. Patient [redacted] (DOB [redacted]; CAHABA GBA PART B ID # [redacted]): The office visit notes state that this patient has low back pain that radiates to his left buttocks, thigh, knee, calf, ankle, foot, and toes as well as low back pain that radiates to his right buttocks, groin, thigh, hamstring, knee, calf, ankle, foot, and toes (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations on this patient.

433. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office visit notes state that this patient has low back pain that radiates to various parts of her lower body including bilateral leg, buttocks, hip, thigh, knee, calf, and ankle (i.e., radiculopathy). Even though the patient did not

qualify, Dr. Ellner also performed facet joint injections and RF Ablations on this patient.

434. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The office visit notes state that the patient has low back pain that radiates to her right buttocks, thigh, knee, calf, ankle, and foot (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations.

435. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office visit notes state that the patient has neck pain that radiates to her shoulders (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections on this patient.

436. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office visit notes state that the patient has low back pain that radiates to her right thigh, hamstring, knee, and foot (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections on this patient.

437. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office visit notes state that the patient has low back pain that radiates to his buttocks, hip, and thigh (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations on this patient.

438. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The office visit notes state that this patient has neck pain that radiates to her left shoulder and occipital (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations.

439. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office visit notes state that this patient has low back pain that radiates from her right hip, thigh, and knee (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed facet joint injections and RF Ablations on this patient.

440. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The office visit notes state that this patient has radiculopathy and has been experiencing this pain for only two months. Dr. Ellner performed facet joint injections and RF Ablations on this patient.

2. Failure to document/perform diagnostic MBB

441. Because of the high error rate associated with facet joint injections, the Palmetto GBA LCDs require the physician to perform two MBBs ("MBBs") to diagnose facet pain before performing a facet joint injection. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-

details.aspx?LCDId=36471.

442. The patient charts referenced below demonstrate that Dr. Ellner failed to perform two MBBs for patients prior to performing facet joint injections. Because the LCDs prohibit reimbursement under these conditions, GPM improperly received and retained monies to which it was not entitled.

443. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

444. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

445. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

446. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

447. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

448. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

449. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

450. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

451. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

452. Patient [redacted] (DOB [redacted]; Patient has Aetna [redacted]; Patient has Medicare [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

453. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's operative report does not document that prior to receiving a facet joint injection, two MBBs were used to diagnose facet pain.

3. Failure to confirm the absence of non-facet pathology

454. Prior to ordering a facet joint injection, the Palmetto GBA LCDs require the physician to rule out the possibility that non-facet pathology is the source of the patient's pain (e.g., fracture, tumor, infection, or significant deformity). Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The patient's file should contain a summary of pertinent diagnostic tests or procedures the physician conducted to arrive at this determination. *Id.*

455. GPM failed to perform the requisite diagnostic tests or procedures prior to ordering facet joint injections, as reflected by the absence of any documentation denoting that these services were in-fact performed.

456. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's first imaging was performed on January 30, 2018. However, Dr. Ellner performed the facet joint injections and RF Ablations on January 4, 2018.

457. Patient [redacted] (DOB [redacted]; UHCID # [redacted]): The patient's office visit note indicates that the patient has not had any recent lumbar imaging. Dr. Ellner, ordered the X-ray after the injection was

performed.

4. Failure to abide by pain threshold and timeline

458. The LCDs require the patient to have been in moderate to severe pain with functional impairment for over three months before administering a facet joint injection. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471.

459. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): On the procedure notes, it states that the patient was experiencing pain of "0" on the pain scale at the time of the procedure. The procedure notes also state: "The pain occurred gradually. This problem has occurred for one week ago." The requirements for the procedure have not been met.

460. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): On the procedure note, it states that the patient was experiencing pain of "1" on the pain scale at the time of the procedure. The requirements for the procedure have not been met.

461. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): On the procedure note, it states that the patient was experiencing pain

of "4" on the pain scale at the time of the procedure. The requirements for the procedure have not been met.

5. Failure to order conservative treatment prior to ordering facet joint injections

462. For a facet joint injection to qualify for coverage, a patient must experience pain inadequately responsive to conservative care (e.g., NSAID regimen, acetaminophen, physical therapy). Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following patient example demonstrates that GPM administered and received reimbursement for facet joint injections without first ruling out the effectiveness of conservative care options.

463. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The patient had not participated in any conservative treatment. The patient was not referred out for physical therapy, NSAIDs, chiropractic care, etc.

B. Radiofrequency Ablations

464. RF Ablation is a minimally invasive procedure aimed at reducing pain experienced in the spine. Ray M. Baker, *Radiofrequency Ablation Procedure*, SPINE-HEALTH (last updated May 24, 2013), https://www.spine-health.com/treatment/injections/radiofrequency-ablation-procedure.

Radiofrequency waves projected from a needle are used to create a heat lesion in the nerve to disrupt the nerve's ability to send pain signals. *Id.*

1. Contraindication radiculopathy

465. As with facet joint injections, Palmetto GBA has deemed RF Ablations medically necessary only when the patient presents with non-radicular pain. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following patient examples demonstrate that GPM routinely administered and received reimbursement for RF Ablations even though the patient reported symptoms clearly indicating radiculopathy.

466. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The patient's office visit notes state that this patient has neck pain that radiates to her left shoulder and occipital. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

467. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The patient's office visit notes state that this patient has low back pain that radiates to his thigh, hamstring, knee, calf, ankle, foot, and toes. Dr. Ellner

performed an RF Ablation on the same day that the patient described his radiculopathy.

468. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): Non-radicular pain is never introduced when describing the patient's pain. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

469. Patient [redacted] (DOB [redacted]; CAHABA GBA PART B ID # [redacted]): The patient's office visit notes state that this patient has low back pain that radiates to his left buttocks, thigh, knee, calf, ankle, foot, and toes. Then, the office note states that he has low back pain that radiates to his right buttocks, groin, thigh, hamstring, knee, calf, ankle, foot, and toes. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

470. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The patient's office visit notes state that this patient has low back pain that radiates to various parts of her lower body, including bilateral leg, buttocks, hip, thigh, knee, calf, and ankle. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

471. Patient [redacted] (DOB [redacted]; UHC ID # [redacted]): The patient's office visit notes state that this patient has low back pain that radiates

to her right buttocks, thigh, knee, calf, ankle, and foot. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

472. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The patient's office visit notes state that this patient has low back pain that radiates to his buttocks, hip, and thigh. Dr. Ellner performed RF Ablations on this patient knowing that the patient did not have the required criteria set forth by Medicare.

473. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]): Dr. Ellner performed procedures where radiculopathy was present when he performed an RF Ablation. Even though the patient did not qualify, Dr. Ellner performed an RF Ablation.

474. Patient [redacted] (DOB [redacted]; TRICARE ID # [redacted]): The office visit notes state that this patient has neck pain that radiates to his left leg and buttocks (i.e., radiculopathy). Even though the patient did not qualify, Dr. Ellner performed an RF Ablation.

2. Failure to document/perform diagnostic MBBs

475. Palmetto GBA requires that two MBBs be performed prior to an RF Ablation. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy

(L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471.

476. Dr. Ellner failed to either perform or document these procedures prior to performing RF Ablations.

477. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): On the operative report, it does not indicate that the patient had 2 MBBs prior to the procedure.

3. Failure to confirm the absence of non-facet pathology

478. Prior to ordering an RF Ablation, the Palmetto GBA LCDs require the physician to rule out the possibility that non-facet pathology is the source of the patient's pain (e.g., fracture, tumor, infection, or significant deformity). Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The patient's file should contain a summary of pertinent diagnostic tests or procedures the physician conducted to arrive at this determination. *Id.*

479. GPM failed to perform the requisite diagnostic tests or procedures prior to ordering RF Ablations, as reflected by the absence of any documentation denoting

that these services were in-fact performed.

480. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The first imaging that was performed for this patient was on January 30, 2018. The procedure was performed on January 4, 2018.

4. Failure to abide by pain threshold and timeline

481. As with facet joint injections, the Palmetto GBA LCDs require that the patient have been in moderate to severe pain with functional impairment for over three months before performing an RF Ablation. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471.

482. Patient [redacted] (DOB [redacted]; UHC Medicare ID # [redacted]): This patient had six procedures performed where he was between a "0" and a "2" on the pain scale. The patient was in no pain reporting a "0" on the pain scale at the time of one of the procedures. The patient was only experiencing a "1" on the pain scale making another procedure not medically necessary according to Medicare. The patient was only experiencing pain at a "2" on the pain scale for yet another procedure.

483. Patient [redacted] (DOB [redacted]; CAHABA ID #

[redacted]): This patient's procedure notes state that the patient was experiencing pain between "3" and "4" on the pain scale at the time of these procedures.

5. Failure to Order Conservative Treatment Prior to Ordering Radiofrequency Ablations

484. As with facet joint injections, a patient's pain must be inadequately responsive to conservative care (e.g., NSAID regimen, acetaminophen, physical therapy) in order for an RF Ablation to qualify as medically necessary. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following patient example demonstrates that GPM administered and received reimbursement for RF Ablations without first ruling out the effectiveness of conservative care options.

485. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The patient was not referred out for physical therapy, NSAIDs, chiropractic care.

6. Repeat or continued procedures after results indicated ineffectiveness

486. Because the clinical efficacy of facet joint injections remains unproven, Palmetto GBA only authorizes physicians to proceed to an RF Ablation if the required dual MBBs provide the patient significant pain relief. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and

Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. Additionally, Palmetto GBA only considers repeat RF Ablations medically necessary where the patient experienced pain reduction of 50 percent or greater and improvement in patient specific activities of daily living for at least six months. *Id.* The following patient examples demonstrate that Dr. Ellner either impermissibly administered RF Ablations in the first instance when the patient did not report significant pain relief from diagnostic injections or ordered repeat RF Ablations where the patient did not experience the requisite pain reduction.

487. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): Patient had 0% relief (The pre-procedure pain described as 4 out of 10. The post procedure pain was described as 4 out of 10. The patient received approximately 0% of relief from the anesthetic.). The patient also stated that she had 20% relief (21 days later) from that same procedure. Then the day of the RF procedure, Dr. Ellner changed the effectiveness to 50% to try to establish false medical necessity and positive results. Dr. Ellner still performed the RF Ablation even though two records stated the patient did not have sufficient relief. On multiple office notes, it is indicated that the patient's facet joint injection was "ineffective."

488. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): The RF Ablation should not have been performed since the patient

experienced 30% relief from the previous RF Ablation. This patient also had several SI joint injections performed. The procedure was not medically necessary because Dr. Ellner notated that the previous SI injection was ineffective.

489. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): It is indicated that the patient's lumbar RF Ablation performed was ineffective. The repeated RF Ablation was not medically necessary.

490. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): Patient had 0% relief as shown (The pre-procedure pain described as 5 out of 10. The post procedure pain was described as 5 out of 10.). Dr. Ellner still performed the RF Ablation.

C. Epidural Steroid Injections

491. An epidural steroid injection is a procedure commonly used to treat radicular pain experienced in the back. Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148. The procedure involves injecting a solution of steroidal and aesthetic agents into the epidural space. *Id.*

1. Failure to document radiculopathy

492. Lumbar epidural steroid injections are generally performed as a method of treating radiculopathy, and as such, Palmetto GBA requires the treating physician to suspect radicular pain in the patient before proceeding with this treatment option.

See Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148. The following patient examples demonstrate that GPM routinely administered and received reimbursement for lumbar epidural steroid injections where the patient failed to describe radicular pain.

493. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): Dr. Ellner clearly stated that the patient's pain does not radiate. Despite this contraindication, Dr. Ellner ordered the patient a caudal epidural steroid injection.

494. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): According to the office visit note on the same day that the epidural was performed, this patient had no radicular pain. The epidural procedure was not medically necessary.

495. Patient [redacted] (DOB [redacted]): According to the office visit note on April 9, 2018, Dr. Ellner notated that the patient was not experiencing any radicular pain. This creates a contraindication to perform this procedure.

2. Failure to use confirmatory imaging

496. In order for a lumbar epidural steroid injection to qualify for Medicare

coverage, the physician must have performed substantial imaging to confirm the presence of physiological abnormalities in the lower back. Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148.

497. The patient charts provided by Relator demonstrate that Dr. Ellner failed to conduct these imaging procedures prior to ordering and performing epidural steroid injections.

498. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): This patient had procedures without proper diagnostic tests. In fact, this patient's last MRI was performed in 2012 as noted on her chart. Even though this patient had not had a diagnostic imagining study performed within the last twelve months prior to these procedures, Dr. Ellner performed the procedures.

499. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient had no imagining for his abnormalities of either foraminal or central spinal canal stenosis prior to the lumbar epidural steroid injection being performed.

500. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): This patient had no recent imaging prior to the caudal epidural steroid injection performed.

3. Failure to abide by conservative treatment requirements

501. For lumbar epidural spinal injections to qualify for Medicare coverage, Palmetto GBA requires physicians to first rule out the efficacy of non-surgical, non-injection care. Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148. Absent limited exigent circumstances, conservative treatment options must fail to provide pain relief for a period exceeding four weeks before a physician may order a lumbar epidural spinal injection. *Id.* Despite this clear requirement for coverage, Dr. Ellner routinely ordered lumbar epidural spinal injections for patients without first requiring patients to undergo four weeks of conservative care. This departure from the LCD requirements renders these claims medically unnecessary and not entitled to reimbursement.

502. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): This patient did not participate in any conservative treatment prior to procedures performed. This patient also did not participate in any conservative treatment prior to any of the injections.

503. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office note indicates that the patient has not participated in any conservative treatment.

504. Patient [redacted] (DOB [redacted]; AARP Medicare ID # [redacted]): This patient's office note indicates that she has not tried any conservative/non-invasive treatment prior to the ESI performed. The patient's note also states that she has not participated in conservative treatment.

505. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office note indicates that she did not participate in conservative treatment for at least four weeks. The patient's office note does not give any reasons or explanations as to why this patient could not participate in conservative treatment for the entire four weeks.

506. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office note clearly states that the pain occurred gradually with an onset of about two weeks ago. The office note does not give any reasons or explanations as to why this patient could not participate in conservative treatment for at least four weeks.

507. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office notes indicate that he has not tried any conservative/non-invasive treatment prior to the procedures performed. He did not participate in conservative treatment for at least four weeks. The office note also states that he has not participated in conservative treatment. The notes do not give any reasons or explanations as to why this patient could not participate in

conservative treatment.

508. Patient [redacted] (DOB [redacted]): This patient's office notes indicate that he has not tried any conservative/non-invasive treatment prior to the procedures performed. As noted, this patient did not participate in conservative treatment for at least four weeks. The office note also states that he has not participated in conservative treatment and gives no reasons or explanations as to why this patient could not participate in conservative treatments.

509. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): The patient's office notes indicate that she has not tried any conservative/non-invasive treatment prior to the procedures performed. She did not participate in conservative treatment for at least four weeks. The office note also states that she has not participated in conservative treatment and gives no reason or explanation as to why this patient could not participate in conservative treatments.

4. Failure to abide by pain threshold and timeline

510. Palmetto GBA requires that the patient present with moderate to severe pain with functional impairment of "activities of daily living" ("ADLs") for an epidural steroid injection to be covered. These indications for coverage must be documented in the patient's chart for the procedure to qualify for reimbursement. Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at*

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148.

511. Dr. Ellner disregarded this indication for coverage on numerous occasions, thereby receiving payments for services to which he was not entitled.

512. Patient [redacted] (DOB [redacted]; CAHABA ID # [redacted]): This patient's office visit note indicates that the patient was experiencing a pain of "2" on the pain scale at the time of the first procedure. On the procedure note, it states that the patient was experiencing pain of "0" on the pain scale at the time of the second procedure. Even with a pain scale of "0," Dr. Ellner perform the procedure.

513. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office visit note states that the patient was experiencing pain of "0" on the pain scale at the time of the lumbar epidural injection. Even with a pain scale of "0," Dr. Ellner performed the procedure. Prior to the lumbar epidural injection, the patient only experienced pain for 10 days.

514. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office note states that the patient was experiencing pain of "2" on the pain scale at the time of the lumbar epidural and lumbar transforaminal injection. Even with a pain scale of "2," Dr. Ellner performed the procedure on a patient that did not have the required level of pain.

515. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office notes state there are no issues with ADLs. However, Dr. Ellner chose to perform a CESI.

516. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient's office visit note indicates that Dr. Ellner has noted that the patient had no issues with her ADLs. The pain had not been present for at least four weeks.

517. Patient [redacted] (DOB [redacted]; Aetna Medicare ID # [redacted]): This patient has no documentation of functional impairment or her inability to perform her ADLs.

518. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient has no documentation of functional impairment or her inability to perform her ADLs.

5. No signature for "informed consent"

519. Palmetto GBA requires providers to obtain and document the patient's informed consent prior to ordering the injection. Palmetto GBA, Local Coverage Determination (LCD): Lumbar Epidural Steroid Injections (L35148) (effective date Oct. 01, 2015), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35148. The following example demonstrates that Dr. Ellner failed to obtain the patient's informed consent prior to

ordering epidural steroid injection ("ESIs").

520. Patient [redacted] (DOB [redacted]; AARP Medicare ID # [redacted]): The "informed consent" for the initial procedure does not show evidence that it was read and explained to the patient because there is not a signature on the informed consent form from the patient, and there is also no signature of a witness to this being signed and explained thoroughly. The "informed consent" for the second procedure does not show evidence that it was read and explained to the patient because there is not a signature on the informed consent form from the patient, and there is also no signature of a witness to this being signed and explained thoroughly.

D. Medial Branch Blocks

521. A MBB is a procedure used in the diagnosis and treatment of chronic neck and back pain. See Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The procedure involves injecting a mixture of anesthetic and anti-inflammatory medication near the medial nerves connected to a specific facet joint (as opposed to injecting the mixture into the intra-articular joint space, as is the case with facet joint injections). *Id.* The procedure is primarily

diagnostic, meaning that if the patient experiences sufficient pain relief for an adequate period of time, the patient may be a candidate for a subsequent procedure (e.g., facet joint injections, radiofrequency ablations). Ray M. Baker, *Medial Branch Nerve Blocks*, SPINE-HEALTH (last updated Oct. 4, 2013), https://www.spine-health.com/treatment/injections/medial-branch-nerve-blocks.

1. Contraindication radiculopathy

522. As with facet joint injections and RF Ablations, Palmetto GBA has deemed MBBs medically necessary only when the patient presents with non-radicular pain. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following patient examples demonstrate that Dr. Ellner routinely administered and received reimbursement for MBBs even though the patient presented with radicular pain.

523. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The patient's office visit notes state that the patient has low back pain that radiates to her buttocks and hips. Dr. Ellner performed the MBBs on this patient knowing that the patient did not have the required criteria set forth by Medicare.

524. Patient [redacted] (DOB [redacted]): The patient's office visit notes state that the patient has low back pain that radiates to her right buttocks, hip, thigh, hamstring, and knee. Dr. Ellner performed MBBs on this patient knowing that the patient did not have the required criteria set forth by Medicare.

525. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): The patient's office visit notes state that the patient has low back pain that radiates to her bilateral buttocks, hips, and thighs. Dr. Ellner performed MBBs on this patient knowing that the patient did not have the required criteria set forth by Medicare.

2. Failure to abide by pain threshold/timeline

526. In order for a provider to order a second confirmatory MBB, the Palmetto GBA LCDs require the patient to report (and the physician to document) at least a 50 percent reduction in primary pain as evidenced by functional improvement, increased range of motion, and a decreased requirement for pain medications. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. Furthermore, the duration of relief must be consistent with the agent employed. *Id.* The following example shows that Dr. Ellner did not

consider or document the effects of the first MBB before ordering a second. Dr. Ellner's failure to do so renders the second MBB medically unnecessary, and thus, not entitled to reimbursement.

527. Patient [redacted] (DOB [redacted]): This patient did not have an office visit in-between the procedures to review the outcome of the initial injection. Instead, Dr. Ellner proceeded to a second injection without documenting whether the patient had experienced pain reduction, functional improvement, increased range of motion, or a decreased requirement for pain medications over a duration consistent with the administration of the initial injection.

3. Repeat or continued procedures after results indicated ineffectiveness

528. As discussed in the preceding section, the Palmetto GBA LCDs require the patient to report at least a 50 percent reduction in primary pain as a condition precedent to ordering additional MBBs. Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15, 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following example demonstrates that Dr. Ellner ordered a subsequent MBB for a patient where the patient reported more pain after the first MBB. Because the patient failed to report the requisite level of pain reduction, the second medial branch does not qualify as medically necessary. As

such, it is not entitled to reimbursement.

529. Patient [redacted] (DOB [redacted]): This patient did not have positive results from the MBB she had performed on June 30, 2017. In fact, the MBB actually made her feel worse.

4. Failure to order conservative treatment

530. As with facet joint injections and RF Ablations, the Palmetto GBA LCDs stipulate that MBBs only qualify as medically necessary where conservative treatment options have not resolved the patient's primary pain. See Palmetto GBA, Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L36471) (effective date Feb. 15 2016), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36471. The following example shows that Dr. Ellner ordered a MBB for a patient who had not first undergone conservative treatment. Dr. Ellner's decision to disregard this requirement renders the procedure medically unnecessary, and thus, not entitled to reimbursement.

531. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): This patient has not participated in any conservative treatment.

E. Trigger Point Injections

532. A TPI is a procedure designed to relieve pain caused by trigger points (i.e., small knots that form in muscles or fascia causing myofascial pain). Melinda Ratini, *Trigger Point Injection (TPI) for Pain Management,* WEBMD (last reviewed

Mar. 13, 2018), https://www.webmd.com/pain-management/guide/trigger-point-injection.

1. Inadequate supporting documentation for trigger point injection

533. The Palmetto GBA LCDs for TPIs require the physician to document the presence of symptomatic trigger points in the patient's chart. Palmetto GBA, Local Coverage Determination (LCD): Trigger Point Injections (L37635) (effective date Feb. 26, 2018), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37635. The indications for an active trigger point entail "pain at rest . . . pain on palpitation . . . radiation of pain, and . . . a local twitch response." *Id.* The following example demonstrates that at least on one occasion, Dr. Ellner ordered trigger point injections without first documenting the presence of an active trigger point. Dr. Ellner's failure to denote and document an active trigger point renders the order medically unnecessary, and thus, not entitled to reimbursement.

534. Patient [redacted] (DOB [redacted]; Medicare ID # [redacted]): As noted in the patient's chart, there is not sufficient supporting documentation for the procedure performed. In fact, there is absolutely no discussion at all in the office note about the patient's TPI. Therefore, medical necessity cannot be established.

535. All of the conduct alleged in this Complaint is alleged to have occurred "knowingly" meaning with reckless disregard, as that is defined in the FCA, 31

U.S.C. § 3729 and related case law.

IX. Knowledge

536. Congress intended to make it easy to prosecute false claims against the Government so that taxpayers could recoup as much wasted money as possible. One emphasis Congress made in the 1985 amendments was to make sure that FCA cases could be prosecuted when the wrongdoers were merely negligent as to submitting the false claims or otherwise violating the FCA. The 1985 amendments allow for prosecution against any person who acts in "reckless disregard of the truth or falsity of the information" with "no proof of specific intent to defraud" required. 31 U.S.C. § 3729(b)(1). Doctors are notorious for taking the position that they do not understand billing and regulations or have staff to do the billing and understand the regulations. However, the courts, like Congress, have found the FCA knowledge standard only requires gross negligence or negligence plus. *U.S. v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997). This particularly applies to doctors or medical professionals. *Id.* ("In failing 'utterly' to review the false submissions, [the doctor] acted with reckless disregard."). Courts have also clarified that if doctors (or others) are getting paid by the Government, they have an obligation to learn the laws, rules, and regulations. *U.S. v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001) (responsible parties have to "inform [themselves] of [Government] requirements" before claims for payment are submitted). This particularly applies to doctors and medical

professionals filing claims with Medicare. *Id.*

> Indeed, Congress clarified the "knowing" standard in 1986 to emphasize that the government need not prove that the defendant had actual knowledge or a specific intent to submit a false claim, reasoning that this high standard was "inappropriate in a civil remedy" and "prohibited the filing of many civil actions to recover taxpayer funds lost to fraud." The Committee Report further noted that the "actual knowledge" standard precluded the government from "holding responsible those corporate officers who insulate themselves from knowledge of false claims submitted by lower-level subordinates. This 'ostrich-like' conduct which can occur in large corporations poses insurmountable difficulties for civil false claims recoveries."

U.S. ex rel. Bledsoe v. Community Health Sys., 342 F.3d 634, 642 n.6 (6th Cir. 2003) (internal citations omitted).

537. The defendants in this case will take these positions of lack of knowledge and point the finger at staff for culpability. That does not suffice under these established standards because managers and doctors are not allowed to simply ignore billing and regulations. However, in this particular case, any such defense is a complete lie. This is not a case of ignorance, but rather willful actions focused solely on maximizing profits to the doctor.

538. Throughout Relator's tenure she discussed the proper way to bill directly with the owner, management, nurses, medical assistants, and front office staff. She tried to guide them into proper and accurate dictation as well as making sure all procedures were based on medical necessity. However, she was the only one concerned about these things and realized that trying to get Defendants to

properly bill Medicare was a fool's errand. The clear and unchallenged directive of management was to maximize billings and profits, regardless of whether it was illegal or not.

X. Retaliation

539. Relator began her employment with Defendant GPM as a claims specialist on December 6, 2016. Over the course of her tenure working at GPM and SPM, Relator learned of the various fraud schemes described herein. Relator alerted various employees at GPM and SPM to the fraudulent billing practices she discovered—including the owner, Dr. Ellner.

540. For example, once, Relator reported billing fraud to Dr. James Ellner on March 23, 2018. She presented him with specific examples of fraud. Relator asked Dr. Ellner to keep her report confidential as she feared reprisal from Ms. Barnhill and Ms. Drago. Dr. Ellner assured Relator that the information would be kept private, but he revealed her complaints to Ms. Barnhill. Dr. Ellner also claimed that he and other GPM/SPM staff would reform the disputed practices. However, the practices remained unchanged.

541. Direct retaliation for these protected activities occurred in early April 2018 when Dr. Ellner attempted to limit Relator's ability to report fraud and to set her up for discipline. He insisted during a meeting with Relator and Ms. Barnhill that all complaints had to now go through GPM's "chain of command." This verbal

mandate required Relator to direct all her complaints to Ms. Barnhill (whom Relator had already warned Dr. Ellner tended to retaliate against Relator rather than fix the issues).

542. During this same meeting, on April 2, 2018, Relator voiced her concerns more broadly regarding Medicare fraud to both Dr. Ellner and Ms. Barnhill. Dr. Ellner told Relator that all information concerning fraudulent billing practices needed to be kept confidential, stating, "This is private you know, so you can't talk about what we do here outside of [these meetings], because that would be a really bad move." A few days, later after considering this odd experience, Relator told Dr. Ellner that she found his comment threatening and retaliatory. She asked Dr. Ellner that no further threats to her employment be made for discussing possible fraud.

543. This communication had the opposite effect. After receiving Relator's email, Dr. Ellner called a meeting with Relator, Ms. Barnhill, and Ms. Connie "CeeCee" McCain. Dr. Ellner started the meeting by pressuring Relator to state out loud (in front of the ersatz witnesses) that GPM had not engaged in any fraud. He told her that it was going to be "a really big problem" if she did not. Relator told Dr. Ellner that she respectfully disagreed with his assessment of whether fraud had occurred. Dr. Ellner also tried to elicit from Relator a statement that he was not threatening her job. She refused. These responses enraged Dr. Ellner, who

proceeded to berate and demean Relator. Other employees later told Relator that they could hear Dr. Ellner yelling at her from down the hallway.

544. Beginning as early as April 20, 2018, Ms. Barnhill began auditing Relator's computer and printing activity—and only Relator's computer. Ms. Barnhill also subjected Relator to intensive and repetitive questioning as to why she was accessing certain patient files. It was clear that Ms. Barnhill and Dr. Ellner were concerned that Relator was planning to report FCA violations to the government. Ms. Barnhill also ordered Relator to stop accessing patient files unrelated to claim denials, asserting that to do so would constitute a HIPAA violation.

545. Relator spoke to HHS-OIG about her fraud concerns and about the alleged HIPAA issues and reported back to GPM management that HHS told her that there was no HIPAA issue and that GPM was not supposed to retaliate against her for investigating these issues. Shortly after reporting her contact with HHS-OIG, GPM abruptly terminated Relator's employment.

546. Defendant GPM had never reprimanded Relator for work-related issues or performance issues. Relator was never approached about any negative aspect of her work and was never written up or disciplined in any way. In fact, during the meeting between Relator, Dr. Ellner, and Ms. Barnhill on April 2, 2018, both Dr. Ellner and Ms. Barnhill commended Relator for the amazing job she was doing—

especially in light of the fact that her workload had doubled since January of 2018. The only negative feedback Relator ever got was for engaging in protected activity, which was the reason she was harassed, discriminated against, and ultimately fired.

FIRST CAUSE OF ACTION
(False or Fraudulent Claims)
(FCA 31 U.S.C. § 3729(a)(1)(A))

547. Relator hereby incorporates and re-alleges all other paragraphs as if fully set forth herein.

548. As set forth above, Defendants, by and through their agents, officers, and employees, knowingly presented, or caused to be presented to the United States Government numerous false or fraudulent claims for payment or approval, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A).

549. Due to Defendants' conduct, the United States has suffered substantial damages.

550. The United States is entitled to treble damages based upon the amount of damage sustained by her in an amount that will be proven at trial.

551. The United States is entitled to the largest civil penalty allowed by law for each of the false claims.

552. Relator is also entitled to her attorney's fees and litigation expenses.

SECOND CAUSE OF ACTION
(False Statements)
(FCA 31 U.S.C. § 3729(a)(1)(B))

553. Relator hereby incorporates and re-alleges all other paragraphs as if fully set forth herein.

554. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B).

555. Due to Defendants' conduct, the United States has suffered substantial damages.

556. The United States is entitled to treble damages based upon the amount of damage sustained by it in an amount that will be proven at trial.

557. The United States is entitled to the largest civil penalty allowed by law for each of the false claims.

558. Relator is also entitled to her attorney's fees and litigation expenses.

THIRD CAUSE OF ACTION
(Failure to Repay)
(FCA-31 U.S.C. § 3729(a)(1)(G))

559. Relator hereby incorporates and re-alleges all other paragraphs as if fully set forth herein.

560. As set forth above, Defendants, by and through their agents, officers, and employees, knowingly made, used, or caused to be made or used a false record

or statement material to an obligation to pay or transmit property or money to the United States Government and knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit property or money to the United States Government in violation of the FCA, 31 U.S.C. § 3729(a)(1)(G).

561. Due to Defendants' conduct, the United States has suffered substantial damages.

562. The United States is entitled to treble damages based upon the amount of damage sustained by it in an amount that will be proven at trial.

563. The United States is entitled to the largest civil penalty allowed by law for each of the false claims.

564. Relator is also entitled to her attorney's fees and litigation expenses.

FOURTH CAUSE OF ACTION
(Retaliation Against Relator)
(FCA-31 U.S.C. § 3730(h))

565. Relator hereby incorporates and re-alleges all other paragraphs as if fully set forth herein.

566. Defendant GPM violated Relators rights pursuant to 31 U.S.C. § 3730(h) by retaliating against her for lawful acts done by her in furtherance of her efforts to stop one or more violations alleged in this action and other protected activities.

567. As a result of Defendant GPM's actions, Relator has suffered damages in an amount to be shown at trial.

568. Relator is entitled to two times back pay, interest, reinstatement, and make whole damages as well as all attorney's fees and litigation expenses.

PRAYER FOR RELIEF

WHEREFORE, Relator Amy Tyson's prayer for judgment:

a. awarding the United States damages sustained by her for each of the false claims;

b. awarding the United States treble damages sustained by her for each of the false claims;

c. awarding the United States the largest civil penalty allowed by law for each of the false claims;

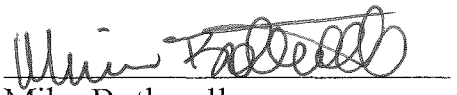
d. awarding Relator 30% of the proceeds of this action and any alternate remedy or the settlement of any such claim;

e. awarding Relator two times back pay, interest, reinstatement, and make whole damages resulting from retaliation;

f. awarding Relator her litigation costs and reasonable attorney's fees; and

g. granting such other relief as the Court may deem just and proper.

Respectfully submitted,



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